

REMARKS

Claims 1-10 and 26-30 are currently pending in this application. Applicant has carefully reviewed the Office Action and respectfully requests reconsideration of the claims in view of the remarks presented below.

Claim Rejections Under 35 U.S.C. §103

Claims 1-10 and 26-30 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,438,408 (Mulligan).

Mulligan was cited for disclosing the recording of information related to procedures performed by a care giver during a follow-up consultation with a patient having an implanted device. Independent claim 1 recites, "recording into the external programming system, information related to the procedures performed between the external programming system and an implanted device during the follow-up consultation, wherein the recorded information comprises the sequence in which procedures are performed between the external programming system and an implanted device."

The purported disclosure in Mulligan, of recording information related to procedures performed by a care provider during a follow-up consultation with a patient having an implanted device (Fig. 4, column 1, lines 15-22), as cited in the Office Action, involves parameter data, *e.g.*, blood pressure, heart chamber volume (column 16, lines 50-54) and related data, *e.g.*, heart rate and patient activity level (column 17, lines 6-7), that are accumulated in the implanted device and periodically transmitted to an external programmer for display and analysis (column 17, lines 17-18). None of this data corresponds to Applicant's claimed "recorded information" which includes the sequence in which procedures are performed between the external programming system and an implanted device. Thus, Mulligan does not disclose the "recording" feature of claim 1.

Mulligan was further cited as disclosing analyzing procedures, and recommending one or more procedures for subsequent follow-up consultation. Claim 1 recites "analyzing the recorded information using software resident within the external

programming system; and based at least in part on the analyzing, presenting information through the external programming system, the presented information indicative of a recommended sequence of procedures to be performed between the external programming system and an implanted device during a subsequent follow-up consultation with a patient having an implanted device.”

The purported disclosure in Mulligan of analyzing procedures, and recommending one or more procedures for subsequent follow-up consultation (column 9, lines 19-37; column 17, lines 12-42), as cited in the Office Action, involves physician analysis of parameter data – not sequences of procedures – to determine if present therapy is effective and if therapy changes are needed. This type of analysis and recommendation, which is based on parameter data, *e.g.*, blood pressure, heart chamber volume, is not the same as Applicant’s analysis of recorded information which includes the sequence in which procedures are performed between the external programming system and an implanted device, and Applicant’s recommended sequence of procedures to be performed between the external programming system and an implanted device. Thus, Mulligan does not disclose the “analyzing” and “recommending” features of claim 1.

Mulligan was also cited as disclosing the presenting of information indicative of a recommended sequence of procedures for follow-up. The information disclosed in Mulligan is in the form of physician advice, which was construed by the Examiner as an output from the physician, indicative to the patient. The Office Action states that while Mulligan does not expressly disclose that the recording and analysis of information be carried out exclusively between an external programmer and an implanted device, it does disclose the input, analysis and recommendation of follow-up procedures by a physician. Based on this, it was concluded that it would have been obvious to use an external programmer to perform and store steps, since it has been held that broadly providing a mechanical or automatic means to replace manual activity which has accomplished the same result involves only routine skill in the art.

The purported disclosure in Mulligan of physician recommendations (column 16, lines 5-67), as cited in the Office Action, corresponds to physician advice to the patient to undertake certain activities at precise times of the day or to initiate determination of parameters using a programmer. Claim 1 recites “presenting information through the external programming system, the presented information indicative of a recommended sequence of procedures to be performed between the external programming system and an implanted device during a subsequent follow-up consultation with a patient having an implanted device.” Physician recommendations described in Mulligan are, first of all, not presented through an external programming system. More significantly, the physician recommendations in Mulligan are not in any way indicative of a recommended sequence of procedures to be performed between the external programming system and an implanted device during a subsequent follow-up consultation with a patient. Thus, Mulligan does not disclose the “presenting information” feature of claim 1.

Mulligan also does not disclose the “repeating” feature of claim 1. This feature was not even addressed in the Office Action.

For each of the reasons presented above, Applicant submits that the subject matter of claim 1 is patentable over Mulligan. Accordingly, Applicant requests reconsideration of the §103 rejections of claim 1 and dependent claims 2-10.

Regarding independent claim 26, it is believed novel over Mulligan for the same reasons presented above with respect to claim 1. Also, it is noted that the purported disclosure in Mulligan of means for recording (column 6, lines 1-8, IMD memory); means for analyzing the procedures (Fig. 2, microcomputer 102 and input signal processing circuit 108); statistical analysis software (column 12, lines 44-67); and means for recommending one or more procedures (telemetry transceiver 124 and antenna 28), as cited in the Office Action, are all part of an implantable device. Thus, Mulligan does not disclose Applicant's claimed external programming system.

Furthermore, several structure features recited in claim 26 are lacking in Mulligan. For example, Mulligan does not disclose an input operative to input to the

memory device, information related to procedures performed between the external programming system and one or more implanted devices during a plurality of follow-up consultations, wherein the recorded information comprises the sequence in which procedures are performed between the external programming system and the one or more implanted devices; and an output operative to output one or more recommended sequence of procedures to be performed between the external programming system and an implanted device during a subsequent follow-up consultation, based at least in part on a statistical analysis of the procedural information performed using the statistical analysis software.

In view of the foregoing, Applicant submits that independent claim 26 is patentable over Mulligan. Accordingly, Applicant requests reconsideration of the §103 rejection of independent claim 26 and dependent claims 27-30.

Claims 1-6, 9, 10, and 26-30 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,405,087 (Snell).

Snell was cited as disclosing the method of claim 1 and the apparatus of claim 26 as substantially claimed except for the recording and analysis of information carried out exclusively between an external programmer and an implanted device. Snell was further cited for allegedly disclosing the input, analysis and recommendation of follow-up procedures by a physician. Based on this, it was concluded that it would have been obvious to use an external programmer to perform and store steps, since it has been held that broadly providing a mechanical or automatic means to replace manual activity which has accomplished the same result involves only routine skill in the art.

The purported disclosure in Snell of the claim elements (the Abstract, figures 1 and 2 and column 8, lines 16-30), as cited in the Office Action, involves performance data, *e.g.*, paced and sensed heart rate histograms, sensor rate histograms, etc., generated by an implanted device and limit data, *e.g.*, thresholds, established and stored either in the implantable device or in the external programmer (column 2, lines 24-35 and column 7, lines 42-56). The performance data and limit data are analyzed by either the implanted device or the external device (column 8, lines 1-6). Thus, with

respect to any recording of data in an external programmer, it is inherent in Snell that such data corresponds to performance data that is generated by an implanted device. Independent claim 1 recites, “recording into the external programming system, information related to the procedures performed between the external programming system and an implanted device during the follow-up consultation, wherein the recorded information comprises the sequence in which procedures are performed between the external programming system and an implanted device.” The external programmer in Snell is not described as having recorded into it, information related to procedures performed between the external programming system and an implanted device, wherein the information comprises the sequence in which procedures are performed between the external programming system and an implanted device. Thus, Snell does not disclose the “recorded information” recited in claims 1 and 26. Because Snell does not disclose the recording of Applicant’s claimed “recorded information,” it cannot reasonably be interpreted as disclosing the analysis of such information, as also recited in claims 1 and 26.

The purported disclosure in Snell of physician recommendations (column 8, lines 16-30), as cited in the Office Action, corresponds to physician advice to himself to modify device programming toward achieving expected performance. Claim 1 recites “presenting information through the external programming system, the presented information indicative of a recommended sequence of procedures to be performed between the external programming system and an implanted device during a subsequent follow-up consultation with a patient having an implanted device.” Physician recommendations described in Snell are, first of all, not presented through an external programming system. While they may be determined based on information displayed on a screen, the recommendations themselves are not in any way presented through an external programming system. More significantly, the physician recommendations in Snell are not in any way indicative of a recommended sequence of procedures to be performed between the external programming system and an implanted device during a subsequent follow-up consultation with a patient. Thus, Snell does not disclose the “presenting information” feature of claims 1 and 26.

In view of the foregoing, Applicant submits that independent claims 1 and 26 are patentable over Snell. Accordingly, Applicant requests reconsideration of this §103 rejections of independent claims 1 and 26 and their respective dependent claims.

Claims 1-3, 5-6 and 8-10 and 26-30 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent Application No. 2003/0171789 (Malek).

Malek was cited as disclosing, among other things, the recommending of one or more procedures for follow-up, wherein the “procedures inherently contain a sequence of steps or procedures.” Malek was further cited for allegedly disclosing the input, analysis and recommendation of follow-up procedures by a physician. Based on this, it was concluded that it would have been obvious to use an external programmer to perform and store steps, since it has been held that broadly providing a mechanical or automatic means to replace manual activity which has accomplished the same result involves only routine skill in the art.

Malek discloses an implantable medical device that may be programmed using a two-phase process including a screening phase and an implant phase. During the screening phase, an external stimulation system is used to adjust stimulation parameters. Parameter settings from the external system are provided to a physician programmer for subsequent download to the implanted device during the implant phase. During the implant phase, the parameters may be changed by the physician or programmer, if needed. See paragraphs [0035] and [0051] and figure 9. Regarding the storage of information, Malek only discloses the storage of parameter settings, user-entered data, patient diagnostic data, system diagnostic data, device usage data, data regarding the last session between the programmer and external system, the state of the external system, and the configuration of the implanted device. See paragraph [0030]. It is noted that none of this stored data is related to procedures performed between an external programming system and the implanted device and furthermore, that procedural steps are not inherent in any of this stored data, as stated in the Office Action. Accordingly, Applicant submits that Malek does not disclose, either explicitly or implicitly, the storage or recording of information indicative of a sequence of procedures

performed between any one of the external system and the implanted device, the physician programmer and the implanted device, or the patient programmer and the implanted device.

Regarding the purported disclosure of physician analysis and physician recommendation based on such analysis, mentioned in the Office Action, Applicants submit that Malek does not describe or suggest any such activity by a physician. Malek merely teaches that stored parameter settings downloaded to an implanted device may be changed through an external programmer. See paragraph [0052]. Nowhere does Malek describe a physician as analyzing recorded information collected over a plurality of follow-up consultations, *i.e.*, during both a follow-up consultation, and one or more follow-up consultations, as recited in claims 1 and 26. Malek also does not describe a physician as providing recommendations of sequences to be performed during a follow-up consultation that is based at least in part on the analysis of information recorded over a plurality of follow-up consultations, as further recited in claims 1 and 26. Thus, the claimed subject matter is not a mere matter of replacing physician manual activity described in Malek with automated means, as suggested in the Office Action.

For each of the foregoing reasons, Applicant submits that the subject matter of claims 1 and 26 is patentable over Malek. Accordingly, Applicant requests reconsideration of the §103 rejections of claims 1 and 26.

In view of the foregoing analysis of independent claims 1 and 26 in view of Malek, Applicant submits that, by virtue of the incorporation of subject matter recited in their respective independent base claims 1 and 26, dependent claims 2, 3, 5, 6, 8-10 and 27-30 are patentable over Malek. Furthermore, Applicants submit that Malek does not teach or suggest, either via automated or physician-implemented manual means, the features recited in dependent claims 2, 3, 5, 6, 8, 9, 6-9, including: recording information indicative of the sequence of procedures for interrogating the implanted device, as recited in claim 2; recording information indicative of the sequence of procedures for communicating diagnostic data with the implanted device, as recited in claim 3; recording information indicative of the sequence of procedures for rhythm

assessments based on the implanted device, as recited in claim 5; pattern analysis of the recorded sequence information, as recited in claim 8; and comparing the recorded sequence information to previously recorded sequence information, as recited in claim 9.

Claims 1-10 and 26-30 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 7,136,707 (Hall).

Hall was cited as disclosing the method of claim 1 and the apparatus of claim 26 as substantially claimed except for the recording and analysis of information exclusively between an external programmer and an implanted device. Hall was further cited for allegedly disclosing the input, analysis and recommendation of follow-up procedures by a physician and partial automation using an external device. Based on this, it was concluded that it would have been obvious to use an external programmer to perform and store steps, since it has been held that broadly providing a mechanical or automatic means to replace manual activity which has accomplished the same result involves only routine skill in the art.

Hall discloses the recording of programming preferences and procedural test order, to partly automate follow-up procedures for implanted devices. See column 1, lines 9-13. In one embodiment, a programming device is preloaded with executable macros that are subsequently transmitted to an implantable device. See column 2, lines 49-52. The programming device includes a processor that transforms the entry of programming variables into executable macros by recording keystrokes of a programmer operator when the operator enters commands using a keyboard or recording a series of data values entered into fields of a display. See column 1, lines 44-46; column 2, lines 59-61; column 3, lines 32-38. In another embodiment, a menu of previously stored script files corresponding to one of an implanted device or cardiac disorder are displayed on the programmer. See column 4, lines 3-15.

It is noted that while the macros and script files in Hall are described as being for the purpose of automating follow-up procedures, none of the macros or script files are created from information collected over the course of several follow-up consultations.

For example, Hall specifies that the commands entered during a first programming session are transformed into executable macros for use execution during a subsequent programming session. See column 5, lines 23-31. Hall does not disclose the recording of commands during subsequent programming sessions. Because of this, it cannot be construed as disclosing Applicant's "recorded information" which includes: with respect to claim 1, information from both a follow-up consultation (see the "recording" step), and one or more follow-up consultations (see the "repeating" step); and with respect to claim 26, a memory having input therein, information from a plurality of follow-up consultations. Furthermore, because Hall's recorded commands are simply used to create macros that are stored in memory, there is no analysis of the recorded commands using software resident within the programmer, as recited in claim 1, or statistical analysis software, as recited in claim 26.

Regarding the purported disclosure of physician analysis and physician recommendation based on such analysis, mentioned in the Office Action, Applicants submit that Hall does not describe or suggest any such activity by a physician. Hall merely teaches that the macros and/or script files may be based on physician preferences. See column 3, lines 42-43 and column 4, lines 16-22. Nowhere does Hall describe a physician as analyzing recorded information collected over a plurality of follow-up consultations, *i.e.*, during both a follow-up consultation, and one or more follow-up consultations, as recited in claims 1 and 26. Hall also does not describe a physician as providing recommendations of sequences to be performed during a follow-up consultation that is based at least in part on the analysis of information recorded over a plurality of follow-up consultations, as further recited in claims 1 and 26. Thus, the claimed subject matter is not a mere matter of replacing physician manual activity described in Hall with automated means, as suggested in the Office Action.

In view of the foregoing, Applicant submits that the subject matter of claims 1 and 26 is patentable over Hall. Accordingly, Applicant requests reconsideration of the §103 rejections of claims 1 and 26.

In view of the foregoing analysis of independent claims 1 and 26 in view of Hall, Applicant submits that, by virtue of the incorporation of subject matter recited in their respective independent base claims 1 and 26, dependent claims 2-10 and 27-20 are patentable over Hall. Furthermore, Applicants submit that Hall does not teach or suggest, either via automated or physician-implemented manual means, the features recited in dependent claims 6-9, including engaging in statistical analysis of the recorded sequence information, as recited in claim 6; statistical analysis comprising confidence level analysis, as recited in claim 7; pattern analysis of the recorded sequence information, as recited in claim 8; and comparing the recorded sequence information to previously recorded sequence information, as recited in claim 9.

CONCLUSION

Applicant has made an earnest and bona fide effort to clarify the issues before the Examiner and to place this case in condition for allowance. Therefore, allowance of Applicant's claims 1-10 and 26-30 is believed to be in order.

Respectfully submitted,

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Date



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